K122228 1/2

**510 (k) LIGAFIX Interference Screw**

OCT 3 2012

## 510(k) SUMMARY

As required by section 807.92

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| Submitter | SCIENCE FOR BIOMATERIALS<br><br>Sciences et Bio Matériaux<br>ZI du Monge<br>F 65100 LOURDES – FRANCE<br>Registration Number : 3004549189 |
| Contacts | Denis CLEMENT, CEO<br>Tel : +33 (0)5 62 42 21 01<br>Fax : +33 (0)5 62 42 21 00<br>e-mail : denis.clement@sbm-fr.com<br>Regulatory contact: anne.cospin@sbm-fr.com |
| Trade Name | LIGAFIX® Resorbable Interference Screw<br>ComposiTCP® Resorbable Interference Screw |
| 510k | SPECIAL 510K |
| CFR section | 21CFR 888.3030 |
| Classification Name | Fastener, fixation, biodegradable, soft tissue |
| Class | II |
| Product Codes | MAI |
| Device panel | ORTHOPEDIC |
| Legally marketed predicate devices | LIGAFIX® INTERFERENCE SCREW (K050407, K061262, K070507 and K090994) manufactured by SCIENCE FOR BIOMATERIALS |

Description:

LIGAFIX® / ComposiTCP® range of products consists of resorbable cannulated screws available in several models designed for the interference fixation of grafts in anterior cruciate ligament reconstruction.

LIGAFIX® / ComposiTCP® interference bone screw is made of a ceramic (beta-TCP) / polymer (Poly Lactic Acid -PLA) composite.

LIGAFIX® / ComposiTCP® interference screw is available in several sizes and in two beta-TCP/ PLA ratios 60/40 (LIGAFIX® 60/ ComposiTCP® 60) and 30/70 (LIGAFIX® 30/ ComposiTCP® 30)

LIGAFIX® / ComposiTCP® interference bone screws are supplied sterile and individually packaged in double heat sealed pouches.

**The purpose of this 510(k) was to address modifications to the head of certain screw configurations, along with modifications to the cannula to allow use with 1.1mm guide wire. The subject system offers screws in diameters ranging from 7 mm to 12 mm with lengths ranging from 20 mm to 35 mm.**

Intended Use LIGAFIX® / / ComposiTCP® is a cannulated, sterile, single-use, resorbable interference bone screw made of a mixture of tri calcium phosphate (beta-TCP) and Poly Lactic Acid (PLA) designed for the interference fixation of grafts in anterior cruciate ligament reconstruction.

Performance data Mechanical tests and dimensional analysis confirmed that LIGAFIX® / ComposiTCP® screws are biocompatible and presents the requisite strength to provide sustained fixation of the graft.

Substantial equivalence The modifications to LIGAFIX® / ComposiTCP® Interference screw (K050407, K061262, K070507 and K090994) consist of additional references of screw together with the modification of existing references.

The additional LIGAFIX® / ComposiTCP® Interference screws are substantially equivalent to their predicate devices LIGAFIX® / ComposiTCP® Interference screw (K050407, K061262, K070507 and K090994) in terms of intended use, material, design, mechanical properties and function.

Preparation date, October 3, 2012.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 3 2012

SBM Sciences for Bio Materials
% Mr. Denis Clement
ZI du Monge
LOURDES 65100
France

Re: K122228
Trade/Device Name: LIGAFIX Resorbable Interference Screw, ComposiTCP Resorbable Interference Screw
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI
Dated: September 3, 2012
Received: September 5, 2012

Dear Mr. Clement:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

**510(k) Number (if known):** K122228

**Device Name:** **LIGAFIX® RESORBABLE INTERFERENCE SCREW**
**CompositCP® RESORBABLE INTERFERENCE SCREW**

**Indications for Use:**

LIGAFIX® / CompositCP® is a cannulated, sterile, single-use, resorbable interference bone screw made of a mixture of tri calcium phosphate (beta-TCP) and Poly Lactic Acid (PLA) designed for the interference fixation of grafts in anterior cruciate ligament reconstruction.

| Prescription Use ✓ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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